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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,236	12/08/2003	Robert Sixto JR.	ISD-056 C1	2523
36822 7590 04/29/2010 GORDON & JACOBSON, P.C. 60 LONG RIDGE ROAD SUITE 407 STAMFORD, CT 06902				
EXAMINER				
BLATT, ERIC D				
ART UNIT		PAPER NUMBER		
3734				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/730,236

Applicant(s)

SIXTO ET AL.

Examiner

Eric Blatt

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2010.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-9 and 12-26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-4, 7-9 and 12-26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date 3-2-2010
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites "at least one of said plurality of retainer portions is located on each of said first and second arm portions." It is unclear how a single retainer portion may be located on each of the first and second arm portions. For present purposes, this claim will be interpreted as though it reads, "at least one of said plurality retainer portions is located on the first arm portion, and at least one of said plurality of retainer portions is located on the second arm portion."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7-9 and 12-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golyakhovsky et al. (US 4,800,879) in view of Yi (US 5,409,499).

Regarding claims 1, 2, 4-13, 15, 16 and 21, Golyakhovsky discloses a clip comprising first and second arms 2, 1 respectively, and a bridge portion 3 that joins the first and second arms. The first and second arms have respective ends, inward and outwardly facing surfaces, lengths, thicknesses and widths as claimed. There is a retainer 7 extending from second arm 1 comprising hook portions 14a. The width of the retainer appears to be identical to and parallel with the second width of the second arm portion. First arm comprises catch portions 14b. The clip is configurable to an original first configuration in which the retainer extends beyond the tip of the first arm portion substantially parallel to the first and second arm portions. (See Figure 3; the second arm may be rotated such that it runs parallel to the first arm.) The clip is configurable to an applied second configuration in which the tissue piercing tip of the retainer is disposed about or adjacent the tip of the first arm portion. (Figure 1) The retainer is adapted to plastically deform from its orientation in the original first configuration to its orientation in the applied second configuration.

With regard to the recitation that the first and second arm portions and the bridge portion are adapted to maintain a generally U-shaped configuration in which the bridge portion extends through at least 90 degrees in the first and second configurations and while the retainer is plastically deformed between the first and second configurations, Yi teaches a related clip (Figure 1) having arms that undergo a rotation during application similar to that of the Golyakhovsky clip, and teaches that the bridge portion may be formed as a living hinge 12 such that the arms and bridge portion comprise a single continuous piece of material. It would have been obvious to one of ordinary skill in the

art at the time of the invention to modify the apparatus of Golyakhovsky by providing the bridge portion as a living hinge since this was a known alternative and the modification would not have produced unexpected results. Upon replacing the joint 3 with a living hinge as disclosed in Yi, the first and second arm portions combined with the living hinge connecting them would form a substantially U-shaped configuration in the first and second configurations and while the retainer is plastically deformed between the first and second configurations. Also, upon making this modification, the clip would be formed as a single continuous piece of material.

It would have been obvious to have the outwardly facing surfaces be offset from each other by now more than 2 mm since it has been held that it is within the knowledge of one skilled in the art to modify the size of a known device.

The retainer 7 has a length substantially 0.7 to 2 times the dimension between an outside of the first arm and an outside of the second arm. (Figure 8) Alternatively, it would have been obvious to one skilled in the art to modify the length of the retainer since it has been held that where the general parameters of a device are known, determining an optimal range for the functionality of the device requires only routine skill in the art.

Regarding claims 2, 3 and 14, Golyakhovsky does not disclose that the clip is made from a unitary piece of titanium or titanium alloy. Yi discloses that medical clips may be formed from titanium or titanium alloys. (Col. 3, Lines 50-60) So modified, the clip would be substantially stiff. It would have been obvious to one of ordinary skill in the art to make the clip of Golyakhovsky from titanium since it Yi teaches that titanium

was known to be used for clip formation and its used would not have produced unexpected results.

Regarding claims 17-20, hook elements 14a are interpreted to define a plurality of retainers. Regarding claim 20, the claim does not require retainer portions that extend from the first arm. Since the retainer portions that extend from the second arm extend longitudinally beyond the first arm, the clip of Golyakhovsky meets the recited limitations of claim 20.

With regard to claims 21-26, the arms of the Golyakhovsky clip will be parallel before application of the clip to tissue. During application and thereafter, the clip will be in a locked condition wherein the arms will again be parallel to one another. Thus, Golyakhovsky teaches the claimed method with the exception of the claimed clip applier. Yi teaches that it was known to use a clip applier to apply a surgical clip. It would have been obvious to one of ordinary skill in the art at the time of the invention to use an applier to aid in applying the clip. Golyakhovsky discloses that applying the clip involves compressing the target tissue. Since application will be performed by the applier, the applier therefore performs this compression. Golyakhovsky discloses applying the disclosed clip to blood vessels. Upon pushing the clip around a vessel surrounded by tissue during normal use, the retainer will pierce through tissue. With regard to claim 26, as seen in Figure 2, the main portion of the retainer appears to be bent around an angle of approximately 145 degrees while the tip of the retainer extends outward from the profile of the clip. It would have been obvious to one of ordinary skill in the art to bend this extending tip around the surface of the first arm in order to reduce

sharp surfaces on the applied clip that could cause tissue damage. So modified, the retainer would be bent substantially 180 degrees.

Response to Arguments

Applicant's arguments filed 1-14-2010 have been fully considered but they are not persuasive.

Applicant submits that the Golyakhovsky clip is not adapted to maintain a generally U-shaped configuration. Examiner notes that the modified clip as discussed in the body of the rejection may easily maintain the claimed U-shaped configuration. While Golyakhovsky intends for the arms to be capable of moving relative to one another, it is clear from the design of the device that it may also maintain a U-shaped configuration, particularly upon modifying the bridge such that it comprises a living hinge. Applicant additionally argues that the Golyakhovsky clip fails to disclose a retainer which has a tissue piercing tip. Examiner maintains that the tip of the Golyakhovsky retainer is capable of piercing at least some layers of tissue. Applicant also holds that it is improper to combine the Golyakhovsky clip with the Yi teaching of using a living hinge. Examiner maintains that the teaching of a living hinge is highly applicable to the Golyakhovsky clip since a living hinge is a well known functional equivalent to the mechanical hinge mechanism disclosed in the unmodified device.

With regard to Applicant's arguments concerning the dimensions of the clip, Examiner holds that these dimensions would be obvious to one of ordinary skill in the art since it has been held that it is within the knowledge of those skilled in the art to

modify the size and shape of a known device. Examiner additionally notes that the arms of the Golyakhovksy clip may be substantially parallel to one another while the clip is applied to tissue. This will, in fact, typically be the case while the clip is applied.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. B./
Examiner, Art Unit 3734

/TODD E. MANAHAN/

Art Unit: 3734

Supervisory Patent Examiner, Art Unit 3734